

WHAT IS CLAIMED IS:

1. A method of establishing a standardized Herbal BioResponse Array (HBR Array) for an
5 herbal composition comprising:
 - d) selecting a characterized herbal composition;
 - e) exposing a biosystem to a batch of the characterized herbal composition and collecting data
10 on two or more markers, wherein one of the markers is a change in gene expression
determined through the use of a nucleic acid microarray, produced by the steps comprising:
 - iv) producing a cell banking system;
 - 15 v) profiling the gene expression pattern of cells from the cell banking system
before and after exposure to the herbal composition;
 - vi) selecting as markers those genes whose expression levels are changed by
exposure to the herbal composition;
 - 20 f) storing the marker data of step b) as a standardized HBR array.
2. The method of claim 1, further comprising:
 - 25 g) repeating steps b) and c) for one more batches of the herbal composition using two or more
of the same or different markers than used in step b);
 - h) combining the HBR Arrays obtained in steps c) and d); and
 - 30 i) analyzing the combined HBR Array of step e) to generate a standardized HBR Array for
the characterized herbal composition.

3. The method of claims 1 or 2, wherein the characterized herbal composition has at least one known BioResponse.
4. The method of claims 1 or 2, wherein one or more of the following is known for the characterized herbal composition: chemical testing, the part of the plant used, the growing conditions of one or more of the individual herbs in the characterized herbal composition, the pre-harvest treatment of one or more of the individual herbs in the characterized herbal composition, the post-harvest treatment of one or more of the individual herbs in the characterized herbal composition, the post-harvest treatment of the characterized herbal composition, and the relative proportions of the individual herbs in the herbal composition.
5. The method of claims 1 or 2, wherein the cell banking system comprises a master cell bank and a working cell bank.
6. The method of claim 5, wherein the cells of the working cell bank are obtained from the master cell bank.
7. The method of claim 5, wherein the step of profiling the gene expression pattern of cells from the cell banking system before and after exposure to the herbal composition is performed using cells from the working cell bank.
8. The method of claims 1 or 2, wherein the change in gene expression is determined using a nucleic acid microarray.
9. The method of claim 8, wherein the said genes whose expression levels are changed by exposure to the herbal composition are selected based on the criteria of having a signal to noise ratio of about 2.5 or greater in the nucleic acid microarray and having an about 1.5 or greater change in the differential expression ratio.
10. The method of claim 8, wherein data regarding between about 10 and about 20,000 genes whose expression levels are changed is stored as part of the HBR Array.

11. The method of claim 10, wherein data between about 10 and about 1,500 genes whose expression levels are changed is stored as part of the HBR Array.

12. A method of evaluating an herbal composition comprising:

5 a) exposing a biosystem to a batch of the herbal composition and collecting data on two or more markers, wherein one of the markers is a change in gene expression determined through the use of a nucleic acid microarray, produced by the steps comprising:

10 i) producing a cell banking system;

ii) profiling the gene expression pattern of cells from the cell banking system before and after exposure to the herbal composition;

15 iii) selecting as markers those genes whose expression levels are changed by exposure to the herbal composition;

b) comparing the collected marker data with a standardized HBR Array for the same or a substantially same herbal composition as that of the batch herbal composition, wherein the
20 standardized HBR Array contains one of the markers data on gene expression.

13. A method of determining if an herbal composition meets a standard specification comprising:

25 a) exposing a biosystem to a batch of the herbal composition and collecting data on two or more markers, wherein one of the markers is a change in gene expression determined through the use of a nucleic acid microarray, produced by the steps comprising:

30 i) producing a cell banking system;

ii) profiling the gene expression pattern of cells the cell banking system before and after exposure to the herbal composition;

iii) selecting as markers those genes whose expression levels are changed by exposure to the herbal composition;

5 b) comparing the collected marker data with a standardized HBR Array for the same or a substantially same herbal composition as that of the batch herbal composition, wherein the standardized HBR Array contains as one of the markers data on gene expression; and

c) determining which herbal compositions have marker data that is similar to that of the standardized HBR Array within an acceptable level.

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14. The method of claim 113, wherein said determining which herbal compositions have marker data which is similar to that of the standardized HBR Array within an acceptable level is determined quantitatively or qualitatively.

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15. The method of claims 13 or 14, wherein the standardized HBR Array includes an acceptable range of variation for each marker.

16. A method of adjusting the components of a herbal composition so that it meets a standard specification for the same or substantially the same herbal composition, comprising:

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a) exposing a biosystem to a batch of the herbal composition and collecting data on two or more markers, wherein one of the markers is a change in gene expression determined through the use of a nucleic acid microarray, produced by the steps comprising:

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i) producing a cell banking system;

ii) profiling the gene expression pattern of cells the cell banking system before and after exposure to the herbal composition;

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iii) selecting as markers those genes whose expression levels are changed by exposure to the herbal composition;

- b) comparing the collected marker data with a standardized HBR Array for the same or a substantially same herbal composition as that of the batch herbal composition, wherein the standardized HBR Array contains as one of markers data on gene expression, and wherein the standardized HBR Array also includes an acceptable range of variation for each marker;
- c) determining whether the herbal composition has marker data that is within the acceptable level of variation for the standardized HBR Array; and
- d) if the marker data is not within the acceptable level of variation for the standardized HBR Array, adjusting the components of the herbal composition.
17. The method of claim 16, wherein steps (a) through (d) are repeated until the marker data of the herbal composition is within the acceptable level of variation of the standardized HBR Array.
18. A method of changing the components of a herbal composition so that it meets a standard specification of another herbal composition, comprising:
- a) exposing a biosystem to a batch of the herbal composition and collecting data on two or more markers, wherein one of the markers is a change in gene expression determined through the use of a nucleic acid microarray, produced by the steps comprising:
- i) producing a cell banking system;
- ii) profiling the gene expression pattern of cells the cell banking system before and after exposure to the herbal composition;
- iii) selecting as markers those genes whose expression levels are changed by exposure to the herbal composition;
- b) comparing the collected marker data with a standardized HBR Array for the other herbal compositions as that of the batch herbal composition, wherein the standardized HBR Array

contains as one of markers data on gene expression, and wherein the standardized HBR Array also includes an acceptable range of variation for each marker;

- c) determining whether the herbal composition has marker data that is within the acceptable level of variation for the standardized HBR Array; and
- d) if the marker data is not within the acceptable level of variation for the standardized HBR Array, changing the components of the herbal composition.

19. The method of claim 18, wherein steps a) through d) are repeated until the marker data of the herbal composition is within the acceptable level of variation of the standardized HBR Array.

20. A method for predicting the biological activity of an herbal composition comprising:

- a) exposing a biosystem to a batch of the herbal composition and measuring the differential responses of two or more markers, wherein one of the markers is a change in gene expression determined through the use of a nucleic acid microarray, produced by the steps comprising:
 - i) producing a cell banking system;
 - ii) profiling the gene expression pattern of cells the cell banking system before and after exposure to the herbal composition;
 - iii) selecting as markers those genes whose expression levels are changed by exposure to the herbal composition;

wherein the set of differential response measurements constitute an Herbal BioResponse Array (HBR Array) data set;

b) comparing the HBR Array of the batch herbal composition to at least one previously-obtained HBR Array of a characterized herbal composition, wherein the previously-obtained HBR Array contains as one of the markers data on gene expression; and

5 c) predicting the biological activity of the batch herbal composition based on the HBR Array comparison made in step b).

21. A method of measuring the relatedness of a herbal composition to a characterized herbal composition comprising:

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a) exposing a biosystem to a batch of the herbal composition and measuring the differential responses of two or more markers, wherein one of the markers is a change in gene expression determined through the use of a nucleic acid microarray, produced by the steps comprising;

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i) producing a cell banking system;

ii) profiling the gene expression pattern of cells the cell banking system before and after exposure to the herbal composition;

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iii) selecting as markers those genes whose expression levels are changed by exposure to the herbal composition;

wherein the set of differential response measurements constitute an Herbal BioResponse Array (HBR Array) data set;

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b) comparing the HBR Array of the batch herbal composition to at least one previously-obtained HBR Array of a characterized herbal composition, wherein the previously-obtained HBR Array contains as one of the markers data on gene expression; and

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c) determining the relatedness of the herbal composition to the characterized herbal composition based on the HBR Array comparison made in step b).

22. A method for predicting new therapeutic applications of an herbal comprising:

5 a) exposing a biosystem to a batch of the herbal composition and measuring the differential responses of two or more markers, wherein one of the markers is a change in gene expression determined through the use of a nucleic acid microarray, produced by the steps comprising;

i) producing a cell banking system;

10 ii) profiling the gene expression pattern of cells the cell banking system before and after exposure to the herbal composition;

iii) selecting as markers those genes whose expression levels are changed by exposure to the herbal composition;

15 wherein the set of differential response measurements constitute an Herbal BioResponse Array (HBR Array) data set;

b) predicting the new therapeutic applications based on the predicted biological activity of the markers in the HBR Array.

20 23. A method for determining the gene expression profile induced by individual chemical entities in an herbal composition comprising:

25 a) producing a cell banking system;

b) profiling the gene expression pattern of cells from the cell banking system before and after exposure to the herbal composition;

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c) selecting as markers those genes whose expression levels are changed by exposure to the herbal composition and placing into an HBR Array;

5 d) comparing the HBR Array generated in step (c) with a standardized HBR Array for a similar or modified herbal composition;

10 e) determining the relative amounts of the individual chemical entities of the herbal composition; and

f) comparing the amount of the individual chemical entities to the result of step (b) to identify those genes whose expression levels change as the amount of the individual chemical entity in the herbal composition changes.

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24. A method for determining the gene expression profile induced by individual chemical entities in a complex mixture without extracting the chemicals from the complex mixture such as an herbal composition, comprising

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a) producing a cell banking system;

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b) profiling the gene expression pattern of cells from the cell banking system before and after exposure to the herbal composition;

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c) selecting as markers those genes whose expression levels are changed by exposure to the herbal composition;

d) comparing the collected marker data with a standardized HBR Array for a substantially same or modified herbal composition;

- e) characterizing the chemical components of the said herbal compositions;
- 5 f) comparing the identified chemical compositions to identify the differential levels of individual chemical components in herbal compositions;
- g) correlating the differential chemical component amounts with the differential
10 bioresponses in the HBR Array to identify the characteristic bioresponses for each chemical entity.